

CRESCENT® Spinal System**510(k) Summary****October 2013**

NOV 22 2013

I. COMPANY:

Medtronic Sofamor Danek USA, Inc
1800 Pyramid Place
Memphis, Tennessee 38132

II. CONTACT:

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Regulatory Affairs Specialist
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III. PROPRIETARY

CRESCENT® Spinal System

TRADE NAME:**IV. CLASSIFICATION NAMES:**

Intervertebral Fusion with Bone Graft,
Lumbar

COMMON NAME:

Intervertebral Body Fusion Device

CLASS:

II

PRODUCT CODE:

MAX (21 CFR 888.3080)

V. PRODUCT DESCRIPTION:

The subject CRESCENT® Spinal System consists of a variety of hollow intervertebral body spacers featuring a bullet-nosed, anatomically shaped design with axial voids designed to hold bone graft material. The implants may be implanted via a posterior, transforaminal or lateral approach and the procedure may be open or minimally invasive. The subject devices are designed with diamond V teeth across both superior and inferior

surfaces to allow the implant to grip the superior and inferior end plates, thus allowing expulsion resistance. The devices range from 7mm to 15mm in height and 36mm in length. The devices are manufactured from medical grade PEEK-Optima LT1 (polyetheretherketone). These devices also contain Tantalum markers used for imaging purposes.

VI. INDICATIONS FOR USE:

The CRESCENT® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

VII. Summary of the Technological Characteristics:

The subject CRESCENT® Spinal System has the same indications, intended use and fundamental scientific technology as the previously FDA cleared predicates; CRESCENT™ Spinal System K094025 (S.E. 04/26/2010) and CRESCENT® Spinal System Titanium K110543 (S.E. 08/09/2011). The material of subject CRESCENT® Spinal System implant is identical to the predicate CRESCENT™ Spinal System (K094025). The purpose of this submission is to seek clearance for the additional sizes of PEEK implant being added to the CRESCENT® Spinal System.

VIII. Identification of Legally Marketed Devices:

The fundamental scientific technology, design features and indications for use for the subject CRESCENT® Spinal System are identical to the predicate CRESCENT™ Spinal System K094025 (S.E. 04/26/2010) and CRESCENT® Spinal System Titanium K110543 (S.E. 08/09/2011).

IX. Discussion of Non-Clinical Testing:

The widths of the predicate CRESCENT™ Spinal System K094025 (PEEK implants) are 11mm, 12mm and 12.5mm. The subject CRESCENT® Spinal System is for introducing a 14.5mm wide PEEK implant. ASTM F2077 "Test Methods for Intervertebral Body Fusion Devices," defines a worst case intervertebral body fusion device with the smallest footprint and tallest height. Medtronic believes that since the footprint is not reducing, it does not introduce a worst case.

The 14.5mm wide Titanium implants are already cleared by the FDA in the predicate CRESCENT® Spinal System Titanium K110543.

Medtronic believes that the subject 14.5mm wide PEEK implant does not introduce a new worst case scenario, which has been documented in a confirmatory engineering rationale. Medtronic believes that the subject device is substantially equivalent to the predicate device.

X. Conclusion:

An engineering rationale and risk analysis has been completed for the change. Based on the engineering rationale, risk analysis and additional supporting documentation provided in this premarket notification, Medtronic believes the subject system demonstrates substantial equivalence to listed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

Medtronic Sofamor Danek USA, Incorporated
Mr. Ankit K. Shah
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K133216
Trade/Device Name: CRESCENT® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: October 17, 2013
Received: October 18, 2013

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins

for
Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K133216

Device Name: CRESCENT® Spinal System

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices